

aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).

(b) *Classification.* Class II (performance standards).

§ 866.5130 *Alpha*-1-antitrypsin immunological test system.

(a) *Identification.* An *alpha*-1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-1-antitrypsin (a plasma protein) in serum, other body fluids, and tissues. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, *alpha*-1-antitrypsin deficiency has been associated with pulmonary emphysema.

(b) *Classification.* Class II (performance standards).

§ 866.5150 Bence-Jones proteins immunological test system.

(a) *Identification.* A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and plasma. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in urine and plasma, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

(b) *Classification.* Class II (performance standards).

§ 866.5160 *Beta*-globulin immunological test system.

(a) *Identification.* A *beta*-globulin immunological test system is a device that consists of reagents used to measure by immunochemical techniques *beta* globulins (serum protein) in serum and other body fluids. *Beta*-globulin proteins include *beta*-lipoprotein, transferrin, glycoproteins, and complement, and are rarely associated with specific pathologic disorders.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5170 Breast milk immunological test system.

(a) *Identification.* A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

§ 866.5200 Carbonic anhydrase B and C immunological test system.

(a) *Identification.* A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques specific carbonic anhydrase protein molecules in serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]